Results: Population consisted of 78% of males, mean age: 66 yrs ± 11 yrs. Indications were 55.9 % stable angina or silent ischemia and 33.1% ACS. Risk factors were well balanced between the 2 populations: hypertension (68.0% P vs. 68.6% X), hypercholesterolemia (63.0% P vs. 63.4% X), diabetes (30.1% P vs. 28.1% X), insulin-treated diabetes (7.8% P vs. 7.1% X), current smoking (22.0% P vs. 20.9% X). Mean number of stents implanted per patient was 1.7 ±1.1. Procedural success was very high in both groups: 97.6% in recipients of PROMUS Element™ stents and 97.8 % for XIENCE PRIME™. At 30 days, clinical events were TVF 1.2% in P vs. 0.8% in X (p=0.56) including all death 0.6% in P vs.0.5% in X (p=0.99), MI 0.7% in P vs. 0.5% in X (p=0.74) and TVR 0.1 % in P vs. 0.1 in X (p=0.85), Stent Thrombosis (definite and probable) was 0.6% in P vs. 0.2% in X (p=0.21).
Conclusions: Non inferiority in 30-day outcome was observed between the 2 stents; the primary endpoint (12-month outcome) will be available for the meeting.

TCT-16

Incidence, mechanisms and outcome of longitudinal stent deformation (LSD) associated with Element, Resolute, Biomatrix and Xience stents: angiographic and case-by-case review of 1,800 cases.

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Background: The incidence of LSD is unknown. The aims of this study were to estimate the incidence of LSD associated with 4 commonly used DES platforms; to compare the mechanism of LSD across platforms; to estimate the incidence of major complications and assess angiographic procedural factors associated with LSD.
Methods: Angiographic and case details for 1,800 PCI cases were examined individually by a panel 3 experienced interventional cardiologists. This cohort included 450 consecutive PCI procedures associated with the use of Promus Element, Xience V, Biomatrix Flex and Resolute Integrity stents respectively. We classified cases as: no LSD, LSD, and stent not visible. Cases of LSD were classified according to mechanism (guide catheter or secondary device related). Treatment, subsequent clinical outcome and cases in which re-entry of the stent following LSD was difficult were recorded.
Results: LSD was detected in a higher proportion with the Promus Element (3.1%) compared to other platforms (Xience V 0.9%, Biomatrix 0.7%, Resolute 0.7%; p=0.002). Guide catheter related LSD occurred equally in all 4 platforms; Promus Element 1.1%, Xience V 0.9%, Biomatrix 0.7%, Resolute 0.7%; p=0.85. However, 9/24 cases were caused by a secondary device, all of which occurred in the Promus Element stent (p<0.0001). Stent thrombosis occurred in 1 of the 3 cases in which LSD was not identified at the time of procedure. Difficulty re-entering the deformed stent was encountered in 6 cases, all of which were in cases of secondary device impact on Promus Element stents. Univariate predictors of LSD were previous CABG, culprit vessel, ostial involvement and lesion tortuosity. Multivariate predictors of LSD were the Promus Element stent, Guideliner use, post-dilation balloons and number of stents deployed.
Conclusions: LSD is more common than previously reported.LSD in ostial lesions caused by guide catheter or guide catheter extension occurred equally with all platforms. LSD associated with secondary devices only occurred with the Element stent, complicating >3% of procedures where it was frequently associated with difficulty re-entering the deformed stent. However, no sequelae were detected when LSD was recognised and treated.

TCT-17

Current Perspectives On Stent Fractures: Trends, Characteristics And Outcomes From The Food And Drug Administration Manufacturer And User Facility Device Experience Database

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Background: Stent fracture (SF) is associated with restenosis and thrombosis. The contemporary incidence and clinical implications of SF remain uncertain in view of newer drug-eluting stents (DES). The FDA Manufacturer and User Facility Experience Database (MAUDE) is an electronic system that aims to capture voluntarily reported device-related safety issues.
Methods: The MAUDE database was searched from January 2008 through March 2013 for "stent fractures" and "coronary fractures". Data were extracted with respect to types of DES, lesion characteristics, presence of overlapping DES, time from index procedure to SF presentation, clinical presentation of SF, treatments and outcomes of SF.
Results: A total of 126 patients were identified with coronary SF. The median time from index procedure, when available, to SF was 17 months [IQR 6-33]. The majority of patients with SF presented with chest pains and 15.1% had documented acute coronary syndrome. Most of the SF occurred in lesions with at least moderate tortuosity (66%) and calcifications (70%). More than half (57.1%) of the reported SF involved overlapping stents. The observed SF was 41.3% in the LAD, 40.5% in the RCA, 9% in the LCX and 4% in the vein grafts. There were 29 overlapping stents in the left anterior descending (LAD) artery (26.9%), 25 in RCA (23.2%) and 4 in LCX (3.7%), respectively. SF was reported more frequently with Cypher (61.1%), followed by Xience (16.7%), Promus (9.5%), Endeavor (5.6%), Taxus (4.8%) and BMS (2.4%). Almost half of reported SF were treated with another DES (54%), 15% had balloon angioplasty only, 7% underwent CABG, 5% had bare metal stent and another 5% with medical therapy.
Conclusions: Throughout the DES platform evolution, there are continued SF reported. However, Cypher remained the most commonly reported SF in the MAUDE database. In accordance with previous reports, Cypher, LAD, RCA, moderate tortuosity and calcifications, and overlapping stents were a recurrent observation seen with SF.

TCT-18

Clinical and Procedural Predictors and Consequences of Stent Thrombosis Following Drug-eluting Stents for Acute Coronary Syndromes: Results From the ADAPT-DES Study

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Background: Stent thrombosis (ST) remains a major concern in patients with acute coronary syndromes (ACS) treated with drug-eluting stents (DES).
Methods: ADAPT-DES was a multicenter prospective study evaluating outcomes in 8,583 patients treated with DES, aspirin, and clopidogrel, and evaluated with platelet reactivity testing. The frequency and consequences of 1-year ST (definite/probable) were evaluated in the subset of 4,436 patients with ACS (STEMI [n=813], NSTEMI [n=1,250], unstable angina [UA; n=2,373]).
Results: ST within 1 year occurred in 50 patients (1.1%) and was associated with high 1-year rates of mortality (30.4%) and myocardial infarction (82.6%). ST occurred more frequently in patients with PAD (2.3% vs 1.0%, p=0.026), hypertension (1.4% vs 0.4%, p=0.008), STEMI vs NSTEMI/UA (1.9% vs 1.0%, p=0.033), ejection fraction ≤40% (2.4% vs 1.0%, p=0.005), no intravascular ultrasound (IVUS)-guidance (1.4% vs 0.8%, p=0.049), stent size ≤3.0 mm (1.5% vs 0.8%, p=0.049), early versus later generation DES (1.5% vs 0.9%, p=0.043), high platelet reactivity post clopidogrel (PRU >208) (1.8% vs 0.6%, p<0.001), and premature dual antiplatelet therapy (DAPT) discontinuation (4.6% vs 1.0%, p=0.008). Independent predictors of ST by Cox regression are shown in the Table.

Independent Predictors of Stent Thrombosis at 1 Year

	HR	95% CI	p Value
Clinical variables			
Hypertension	3.93	1.53 – 10.12	0.005
STEMI vs NSTEMI/ UA	2.72	1.46 – 5.06	0.002
History of peripheral vascular disease	2.18	1.05 – 4.51	0.040
Angiographic/ procedural variables			
Ejection fraction ≤40%	2.41	1.15 – 5.00	0.020
IVUS-guided stenting	0.49	0.24 – 0.90	0.045
Later vs early generation DES	0.54	0.29 – 1.00	0.050
Other variables			
Premature DAPT discontinuation	5.16	2.57 – 10.34	<0.001
VerifyNow P2Y12 PRU >208	2.92	1.57 – 5.42	<0.001

Separate Cox models were used for clinical, angiographic/procedural, and other variables

Conclusions: ST within 1 year occurs in ~1% of ACS patients treated with DES and is associated with high rates of myocardial infarction and mortality. Strategies that may reduce ST in ACS patients include the use of more potent ADP antagonists, better strategies to achieve DAPT adherence, the use of later generation DES, and optimization of post-stent results with IVUS.

TCT-19

The Impact of Coronary Lesion Severity on Drug-eluting Stent Outcomes in Patients with and without Diabetes Mellitus

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Background: Previous studies have shown conflicting results in regard to efficacy outcomes of drug-eluting stents (DES) in patients with and without diabetes mellitus (DM). Little is known on the impact of baseline lesion complexity on clinical outcomes in these patients.
Methods: Patient-level data from 18 prospective randomized DES trials were pooled (ACUITY; COMPARE; C-SIRIUS; ENDEAVOR 2; ENDEAVOR 3; ENDEAVOR 4; E-SIRIUS; HORIZONS-AMI; RAVEL; SIRIUS; SPIRIT 2; SPIRIT 3; SPIRIT 4; TAXUS 1; TAXUS 2; TAXUS 4; TAXUS 5; TAXUS 6). Propensity-adjusted outcomes according to the presence of DM and lesion complexity (ACC/AHA class A/B1 vs. B2/C).
Results: Among 18,441 randomized patients, 3,467 (19%) had DM. Pts with vs. without DM had higher 1-year rates of TLR (HR [95%CI] = 1.34 [1.05, 1.70]), TVR (HR [95%CI] = 1.40 [1.15, 1.72]) and TVR non-TLR (HR [95%CI] = 1.62 [1.14, 2.31). The 1-year rates of cardiac death or myocardial infarction (MI) were also higher in DM (HR [95%CI] = 1.40 [1.09, 1.81]). As shown in the Table, an interaction was present between DM status and ACC/AHA lesion class on the need for repeat revascularization after DES. There was no interaction between DM status and ACC/AHA lesion class on safety endpoints.
Conclusions: In the DES era, the rates of TLR and TVR after PCI of non-complex lesions are similar in DM and non-DM patients, whereas complex lesions still have higher repeat revascularization rates if DM is present. Compared to non-DM, DM patients continue to have higher rates of clinical restenosis in complex lesions, and of cardiac death and MI in all patients. Despite advances in DES, new strategies are needed for the diabetic patient.

Interaction between diabetic status and lesion complexity for 1-year safety and efficacy outcomes

ACC/AHA lesions	A/B1			B2/C			
	DM	No DM	HR 95%CI	DM	No DM	HR 95%CI	Pinteraction
Efficacy endpoints							
TLR	4.6%	4.8%	0.96 (0.64,1.44	8.0%	4.5%	1.80 (1.39,2.33)	0.01
TVR	7.4%	6.8%	1.13 (0.81, 1.58)	10.6%	5.9%	1.81 (1.45, 2.27)	0.02
Safety endpoints							
Cardiac dearh or MI	3.6%	2.1%	1.71 (1.00-2;93)	5.7%	4.7%	1.22 (0.93,1.60)	0.28
Stent Thrombosis	0.7%	0.3%	2.32 (0.60, 8.97)	1.7%	0.9%	1.87 (1.05, 3.32)	0.78

TCT-20

Two-Year Clinical Follow-Up of the FIREHAWK Abluminal Groove-Filled Biodegradable Polymer Sirolimus-Eluting Stent in the Treatment of Patients with De Novo Native Coronary Artery Lesions: The TARGET I Trial

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Background: This article reports the 2-year clinical outcomes of the abluminal groove-filled biodegradable polymer sirolimus-eluting stent (SES) FIREHAWK (MicroPort Medical, Shanghai, China) compared with the everolimus-eluting stent (EES) XIENCE V in the randomized TARGET I trial.
Methods: A total of 458 patients with single de novo native coronary lesions <=24 mm in length and a coronary artery >=2.25 to <=4.0 mm in diameter were enrolled in the TARGET I study, a prospective, randomized, non-inferiority trial. The primary endpoint was in-stent late lumen loss (LLL) at 9-month follow-up. The secondary endpoint, target lesion failure (TLF), was defined as the composite of cardiac death, target vessel myocardial infarction (TVMI), or ischemia-driven target lesion revascularization (iTLR). Clinical follow-up was scheduled at 1-, 6- and 12-month, and annually up to 5 years for all enrolled patients. All adverse clinical events were adjudicated by an independent committee.
Results: The 9-month in-stent LLL of the FIREHAWK was comparable to the XIENCE V group (0.13±0.24 mm vs. 0.13±0.18 mm, p=0.94; difference and 95% confidence interval 0.00 [-0.04, 0.04] mm; p for non-inferiority <0.0001). After 2 years, the TLF rates were 2.7% and 2.6% in FIREHAWK and XIENCE V group, respectively (p = 0.97). Between 1 year and 2 years, only 1 new iTLR was occurred in each group, with no additional cardiac death and TVMI. No definite / probable stent thrombosis was observed in both groups at 2 years. The major results are shown in the table.